Oregon
John A. Kitzhaber, M.D., Governor

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July 26, 1999
Dockets Management Branch
Food and Drug Administration
(HFA-305), Room 1061
5630 Fishers Lane
Rockville, Maryland, 20852

Re: Docket Number 98N-1265: Federal/State Memorandum of Understanding on Interstate Distribution of Compounded Drug Products

To Whom It May Concern,

On July 21, 1998 at their regularly scheduled meeting The Oregon Board of Pharmacy reviewed the 12/23/98 draft of the *Memorandum of Understanding on Interstate Distribution of Compounded Drug Products Between the [State Agency] and the U.S. Food and drug Administration.* Considerable discussion was held at that time among Board of Pharmacy members, staff and pharmacists in attendance. The Board would like to provide the following comments regarding adoption of the Memorandum of Understanding (MOU).

Two primary concerns have been articulated by the Board. First, it is not clear that a significant public health and safety issue is being addressed by the terms of the proposed agreement. The MOU would implement interstate shipping quotas on products compounded by pharmacists. It would not implement any new qualitative health and safety measures.

Second, the MOU would place additional burdens on State Board staff by requiring the State Boards to investigate complaints. Staff and resources available for inspections and investigations are very limited. Resources are simply not available to inflate the work load of the Oregon Board of Pharmacy to include investigative activities not directly related to public health and safety.

For these reasons, the Oregon Board of Pharmacy would not be interested in adopting the Memorandum of Understanding as it is currently written. The agency appreciates the FDA's decision to extend the comment period. It is in this spirit of cooperation that these comments are provided. Boards of Pharmacy currently provide regulatory oversight of pharmacists and pharmacies in the interest of public health, safety and welfare. The Oregon Board will continue to work closely with the FDA and be a resource whenever possible regarding these issues as they relate to the practice of pharmacy. It is hoped that these comments will be useful in developing a more widely acceptable approach to the regulation of pharmacy compounding services.

Sincerely,

Gary A. Schnabel, R.Ph., R.N.
Executive Director

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98N-1265

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